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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,113	12/21/2000	Hui Wang	3375	2203

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AFFYMETRIX, INC  
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EXAMINER

SIEW, JEFFREY

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/746,113

**Applicant(s)**

WANG ET AL.

**Examiner**

Jeffrey Siew

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 & 24-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The response has amended claims to recite that substantially entire mRNA transcript sequences are detected and refers to the specification at pages 17-19 for example. However the specification does not provide support for extension of substantially full length mRNA and detection of substantially full length mRNAs. Although the specification refers to 3' bias in the art, the specification does not provide adequate support for substantially full length mRNAs.

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2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 & 24-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-20 & 24-31 are indefinite because the term “substantially entire mRNA transcript sequences are detected” is unclear. It is unclear whether the term refers to full length mRNA transcript sequences or entire transcripts of the species of RNA that are present in the sample which may be of different sizes. Moreover, it is unclear as to whether actual full length mRNA transcripts are to be fully extended.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 24,25, 30 & 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Weidenhammer et al (US6,379,897 April 30, 2002).

Weidenhammer teach a method of detecting different RNAs in a sample comprising hybridizing the sample with microarray substrate wherein in substrate has plurality of different

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immobilized probes for primer extension, synthesizing primer extension products with nucleic acid polymerase, appropriate reagents and conditions and detecting extension products to determine level of different RNAs(see entire doc. esp. col. 14 line 16-46 & col. 1 lines 45-55). They teach probes immobilized in 5'-3; direction (see col. 12 lines 27-34). They teach detecting at least 100 RNAs(see col. 9 line 14). They teach using a label (see col 14 line 39). They detect fragments of transcripts (see col. 22 line 23-25).

4. The response filed 3/10/04 has been fully considered and deemed not persuasive. The response has amended claims to recite extension products comprise 5' regions of mRNAs and substantially entire mRNA transcripts are detected.. The specification does not provide explicit definition of the phrases and would not eliminate Weidenhammer as prior art. Weidenhammer et al do teach the entire full length of the gene is detected (see Example 6) in which the entire full length  $\beta$ -1a is amplified and detected. Although Weidenhammer teach detecting 5 regions in that extension of primer is in the 5' direction. The entire transcripts are then detected (see col. 22 line 23-25). The 102 and 103 art rejections based on Weidenhammer are maintained.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6- 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weidenhammer et al (US6,379,897 April 30, 2002) in view of Heller et al (US5,605,662 Feb 25, 1992).

The teachings of Weidenhammer et al are described previously.

Weidenhammer do not explicitly teach synthesis of probes.

Heller et al teach synthesis of probes on substrate within the microlocations of size 50um by 50 um (see col. 12 line 20 & see col. 21 lines 1-43).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Heller et al's synthesis method to Weidenhammer array in order to construct probes. Weidenhammer et al states that Heller et al's teachings of immobilizing probes would apply to their array (see col.12 line 28). Heller et al then states that combinatorial synthesis allows very large numbers of sequences to be synthesized on device (see col. 20 line 60-62). It would have been prima facie obvious to apply Heller et al's synthesis method to Weidenhammer et al's array in order to produce a large number of probes within the microlocations of the microarray.

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Moreover it would have been prima facie to increase the number of probes within the microlocation to detect greater number of different RNA targets.

6. Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weidenhammer et al (US6,379,897 April 30, 2002) in view of Heller et al (US5,605,662 Feb 25, 1992) in further view of Chee et al (US5,837,832 Nov. 17, 1998)

The teachings and suggestions of Weidenhammer et al and Heller et al are described previously.

Weidenhammer et al do not teach tiling.

Chee et al teach tiling (see whole document).

One of ordinary skill in the art would have been motivated to apply Chee et al's tiling technique to the combined invention of Weidenhammer and Heller et al in order to examine regions of genes. It would have been prima facie obvious to apply Chee et al's tiling to Weidenhammer et al's probes in order to detect sequence variation in exon boundaries.

## **SUMMARY**

7. No claims allowed.

### CONCLUSION

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach



## CONCLUSION

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (571)272-0534.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The 1600 Tech Center FAX is (703)-872-9306.

  
JEFFREY SIEW  
PRIMARY EXAMINER

May 24, 2004

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the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

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JEFFREY SIEW  
PRIMARY EXAMINER

May 24, 2004